Supporting Hearing Health for Vulnerable Populations affected and infected by HIV/AIDS using Mobile Technologies

by

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ABBREVIATIONS

HIV	Human Immunodeficiency Virus
AIDS	Acquired Immunodeficiency Syndrome
LMICs	Low-to-middle income countries
CCWs	Community care workers
mHealth	Mobile health
MPANLs	Maximum permissible ambient noise levels
dB HL	Decibels hearing level
kHz	Kilohertz
WHO	World Health Organization
JCIH	Joint Committee of Infant Hearing
AAA	American Academy of Audiology
NPO	Non-profit Organization
WHO	World Health Organization

FORMATTING

APA referencing style was utilized in this dissertation.

ABSTRACT

Access to ear and hearing care is a challenge in low-to-middle income countries (LMICs) where the burden of hearing loss is greatest. This study investigated a community-based programme for detection and diagnosis of hearing loss, using smartphone hearing screening operated by community care workers (CCWs) in vulnerable populations affected and infected by the Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS). This study also surveyed the knowledge and experiences of CCWs providing the service.

The study comprised two phases. In phase one, fifteen CCWs were trained to perform hearing screening during home visits using a validated smartphone application (hearScreen™) with calibrated headphones. Diagnostic follow-up assessments included evaluation using the smartphone test (hearTest™), otoscopy and tympanometry. Phase two included a survey on CCW's knowledge on hearing health and experiences of the hearing screening programme.

276 adults (mean age 30.4 years; range 19 – 70 years; SD 9.1) and 235 children (mean age 8.7 years; range 2 – 18 years; SD 4.1) were tested over an eight-week period. Overall referral rates for adults and children were 5.0% and 4.2% respectively. 75.0% of referred participants returned for follow-up diagnostic assessments, 33.3% of whom were diagnosed with hearing difficulties and referred for further intervention services. All CCWs agreed that community members needed hearing health services and only 6.6% did not want to provide hearing testing as part of their services.

Results of this study indicated that simple smartphone-based hearing screening allows minimally trained CCWs to decentralize hearing services to vulnerable communities in a timely, affordable, and reliable manner, thereby reducing the demands placed on limited ear and hearing health professionals.

Keywords: Community care workers, mHealth, community-based, HIV/AIDS, smartphone, hearing screening, cost-effective, vulnerable, telehealth, time-efficient

CHAPTER 1

INTRODUCTION

The Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) is a worldwide epidemic which continues to devastate and claim the lives of millions of people of all ages (Ssengonzi, 2009). At the end of 2015, approximately 36.7 million people worldwide (0.05% of the global population) were infected with HIV/AIDS, with the vast majority of these individuals living in low-to-middle income countries (LMICs) within sub-Saharan Africa (World Health Organization [WHO], 2017). As a result of the HIV/AIDS pandemic, many of these vulnerable individuals experience serious social, economic, and health consequences (Andrews, Skinner, & Zuma, 2006). Furthermore, the prevalence of hearing loss is substantially higher in LMIC regions than in high income countries. Sub-Saharan Africa alone accounts for 9% of hearing loss globally (World Health Organization [WHO], 2018; World Health Organization [WHO], 2012).

Hearing loss is one of the most frequently occurring non-fatal disabling conditions affecting individuals, communities, and societies worldwide (WHO, 2018). In 2015, approximately half a billion people worldwide were living with a disabling hearing loss, approximately 6 to 8% of the world's population (Wilson, Tucci, Merson, & O'Donoghue, 2017). Additionally, the prevalence of chronic otitis media as well as conductive and sensorineural hearing loss is typically high among HIV-infected children (Ensink & Kuper, 2017; Ndoleriire, Turitwenka, Bakeera-Kitaaka, & Nyabigambo, 2013), especially among those with advanced stages of HIV infection (Swanepoel et al., 2010a; Torre et al., 2012).

In developing countries where illiteracy levels are high and spoken communication is predominantly used, the effects of a disabling hearing loss are even more adverse and dramatic than in developed countries (Swanepoel et al., 2010a). Early identification of a new or developing hearing loss in one or both ears is crucial in order to minimize the associated negative consequences of hearing loss, and should be followed by appropriate referral for intervention (AAA, 2011). Unfortunately, the

majority of such populations live in communities where hearing health care services are inaccessible or severely limited (Mulwafu, Ensink, Kuper, & Fagan, 2017).

The main reasons reported for the lack of hearing health care services within these communities are a shortage of human resources for ear and hearing care, a lack of appropriate equipment, and more urgent health care priorities (Theunissen & Swanepoel, 2008; WHO, 2013). Unfortunately, the number of hearing health providers is precariously insufficient in developing countries, with estimates of only one audiologist per 0.5 million to 6.25 million people in developing countries worldwide; that is, less than one audiologist for every one million people in sub-Saharan Africa (Goulios & Patuzzi, 2008; Mulwafu et al., 2017; Windmill & Freeman, 2013). Within the South African context, the majority of audiologists enter the private health care sector, and are therefore unequally distributed between the private and public health sector (Swanepoel et al., 2009; Swanepoel, 2006). This increases the demand placed on individuals operating in the public health care sector that serves approximately 85% of the population (Swanepoel et al., 2009; Swanepoel, 2006).

Furthermore, HIV/AIDS remains one of the primary causes of adult and child mortality in developing countries (Ssengonzi, 2009). With a generation of children already orphaned with the loss of one or both parents due to HIV/AIDS, the traditional family structure is often no longer in place and many grandparents are left to provide care and support to vulnerable populations (Andrews et al., 2006). Subsequently poverty is deepened within these LMICs due to associated costs both during illness as well as after death, exacerbating the already limited access to hearing health care (Andrews et al., 2006). The HIV/AIDS epidemic and associated increased prevalence of hearing loss necessitate new and improved service delivery models to ensure access to preventative hearing health services.

There are a number of possible options that may improve the accessibility of hearing health services to those in need, particularly vulnerable populations. Evidence suggests that primary health care visits may be the only platform to ear and hearing health services that individuals with hearing loss receive in LMICs (Bogardus, Yueh, & Shekelle, 2003). Unfortunately, there are many barriers to accessing these services within primary health care settings. One apparent barrier is the cost, both in

terms of time and resources, involved in attending clinics, as well as high costs associated with conventional screening and diagnostic audiometric equipment (Swanepoel et al., 2010a). Furthermore, there are limited hearing health professionals available in primary health care clinics (Swanepoel et al., 2010a). Ultimately this highlights the need for a decentralised community-based approach to ensure support for vulnerable households.

A possible approach, recommended as a way to improve access to care, is the use of telehealth (Swanepoel et al., 2010a; Swanepoel, Olusanya, & Mars, 2010b). Telehealth implies health care at a distance, and offers unique opportunities for providing access to ear and hearing health services, such as mobile health (mHealth) using smartphones among other portable devices (Clark & Swanepoel, 2014; Davis & Smith, 2013). Smartphone hearing screening as well as diagnostic testing using the hearScreen™ and hearTest™ applications have been demonstrated to be valid and appropriate for use in primary health care and community-based settings (Mahomed-Asmail, Swanepoel, Eikelboom, Myburgh, & Hall, 2016; Sandstrom, Swanepoel, Myburgh, & Laurent, 2016; Swanepoel, Myburgh, Howe, Mahomed, & Eikelboom, 2014; Van Tonder, Swanepoel, Mahomed-Asmail, Myburgh, & Eikelboom, 2017). Smartphone hearing screening and diagnostic testing offers an inexpensive and mobile alternative to conventional evaluations by utilizing widely available smartphone and headphone technology, and provides time-efficient identification of hearing loss (Louw, Eikelboom, & Myburgh, 2017). No significant difference between test results obtained via conventional behavioural hearing screening and smartphone hearing screening has been reported, with no substantial difference in sensitivity and specificity rates (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014). No significant differences were reported either when using smartphone-based audiometry as compared to conventional audiometry (Sandstrom et al., 2016; Van Tonder et al., 2016).

Furthermore, quality control measures are integrated into the smartphone solutions to monitor environmental noise levels, quality index (QI) of test operator performance, and also to simplify data management, referrals, and reporting (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014; Yousuf Hussein, Swanepoel,

Mahomed, & Biagio de Jager, 2018). These types of mHealth solutions employ simple user interfaces and automated test sequences that allow minimally trained laypersons such as community care workers (CCWs) to render services in communities (Yousuf Hussein et al., 2018; Yousuf Hussein et al., 2016; United Nations Educational, Scientific and Cultural Organization [UNESCO], 2017). Community-based services have been demonstrated to represent a promising platform in the implementation of mHealth-assisted screening programmes (van der Merwe, Mosca, Swanepoel, Glascoe, & van der Linde, 2018). CCWs provide various services for disadvantaged households and allow hearing health care services to be brought to underserved communities at a primary care level (Yousuf Hussein et al., 2016). By directly visiting households, CCWs improve the accessibility of health services and can ultimately reduce the costs involved (Braun, Catalani, Wimbush, & Israelski, 2013). By shifting tasks from highly trained personnel to community members, the demands placed on limited ear and hearing health professionals in LMICs are also reduced (Chadha, 2013; Yousuf Hussein et al., 2018; Yousuf Hussein et al., 2016).

Empowering vulnerable communities through the use of mHealth solutions is a novel approach which promises improved access to primary care services such as ear and hearing health care (Braun et al., 2013). To date, there has been a shortage of research evidence available on community-based programmes for detection and diagnosis of hearing loss, particularly within vulnerable communities in LMICs such as within sub-Saharan Africa where the prevalence of hearing loss is greatest (Chadha, 2013; Yousuf Hussein et al., 2016).

The potential applications and possible impact mHealth solutions delivered by CCWs may provide to underserved communities is significant as such services are not bound by distance or location. Under a decentralized approach to service, mHealth solutions may provide a cost-effective and sustainable means of providing ear and hearing health services to households in LMICs, ensuring timely referral and follow-up rates. The current study therefore investigated the use of an mHealth community-based programme supporting vulnerable populations affected and infected by HIV/AIDS. This study also surveyed the knowledge and experiences of CCWs providing the service.

CHAPTER 2
METHODOLOGY

Institutional review board clearance was obtained from the Research Ethics Committee of the Faculty of Humanities, University of Pretoria, prior to the commencement of data collection (Appendix A).

The study included two phases. The first phase evaluated mHealth community-based hearing detection and diagnosis of children and adults affected and infected by HIV/AIDS. The second phase described CCW knowledge concerning hearing health and experiences of the community-based hearing screening programme.

2.1 PHASE 1: Evaluating mHealth community-based hearing detection and diagnosis

2.1.1 Research aim

To describe a community-based mHealth hearing health care programme in terms of:

a) Coverage rate of hearing screening programme
b) Referral rate of hearing screening programme
c) Reliability of hearing screenings conducted
d) Compliance of the test environment
e) Time proficiency of hearing screenings
f) Diagnostic follow-up return rate

2.1.2 Research design

Phase one of this research study evaluated an mHealth supported community-based hearing detection and diagnosis programme by employing an exploratory, descriptive cross-sectional research design. Exploratory research is used when research is in a preliminary stage and definitive conclusions arising from it are limited (Leedy & Ormrod, 2001; Maxwell & Satake, 2006). This research study was exploratory in nature as minimal research is available on the selected topic.

Quantitative descriptive data was collected cross-sectionally by CCWs who performed hearing screenings on community members as part of their regular home-based visits.

2.1.3 Environment

Data collection was conducted in Sunnyside, an area situated just east of the city centre of Pretoria, South Africa. Hearing screening was conducted in the homes of the participants in the study by 15 CCWs from a non-profit organization (NPO). In the event that a full diagnostic test was needed, participants were referred to the NPO situated in Sunnyside where diagnostic audiometry was performed by the researcher. Diagnostic testing comprised of otoscopy, tympanometry, and diagnostic air conduction pure tone audiometry using the smartphone hearTest™ application.

2.1.4 Participants

Participants were selected from a LMIC community in the City of Pretoria, Gauteng Province, South Africa. Convenience sampling was employed to invite CCWs who form part of an NPO (Appendix B) to participate in this research study (Appendix C). 15 CCWs agreed to take part in the current study. These CCWs provide various services to vulnerable family households during home-based visits. Each CCW was assigned to 20 households and were trained in general ear and hearing health care as well as in conducting hearing screenings.

Following training, this study employed non-probability purposive sampling of 511 community members infected with HIV/AIDS or who had family members infected with HIV/AIDS (Leedy & Ormrod, 2001). All community members invited to participate in this study were residents from the Sunnyside area who already received services from the NPO, such as donations including food parcels and clothing items, as well as various health assessments such as HIV/AIDS screening among others. Both male and female participants over the age of four years were included in this study. Informed consent/assent was also required from participants and from parents/guardians of participants <18 years old (refer to Appendix D, E and F). Hearing screenings were conducted over an eight-week period during which 511 participants were screened.

2.1.5 Materials and apparatus

The following equipment and apparatus were used during this phase:

2.1.5.1 Community-based hearing screening conducted by CCWs

hearScreen™ smartphone application

Data was collected by CCWs using the smartphone hearScreen™ application, version 3.309 (hearX group, Pretoria, South Africa), installed on six Samsung Trend Neo smartphones (Android OS, 4.0) connected to supra-aural Sennheiser HD280 Pro headphones. The hearScreen™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Madsen & Margolis, 2014). Calibration was performed by means of a G.R.A.S. RA0039 artificial ear using a RION NL-52 sound level meter complying with ISO 60318-1:2009 and ISO 60318-2: 1998 (Van der Aerschot, Swanepoel, Mahomed-Asmail, Myburgh, & Eikelboom, (2016).

The hearScreen™ application employs automated test protocols. A sweep was performed at the test frequencies of 1, 2 and 4kHz at an intensity of 25dB HL for children and 35dB HL for adults. Noise levels were recorded and monitored by the smartphone application to avoid exceeding maximum permissible ambient noise levels (MPANLs). A quality index (QI) was also recorded, which indicates the quality of tests conducted by the test operator by reflecting the number of false-positive responses obtained by the test operator when a non-stimulus condition is randomly presented to the participant. A QI score below 70% was flagged for retraining. Test results collected by the smartphone application were immediately uploaded to a secure cloud-based server via a mobile network for data management.

2.1.5.2 Diagnostic audiometry follow-up

Otoscope Welch Allyn

An otoscope was used to visually inspect the participant's outer ear, ear canal, and tympanic membrane to rule out any obvious pathology.

GSI 38 Auto Tympanometer

Tympanometry was conducted to determine the participant's middle ear functioning in terms of middle ear pressure, volume, and compliance (Katz, 2014).

hearTest™ mobile diagnostic hearing testing application

Diagnostic audiometry was conducted by the researcher using the hearTest™ mobile diagnostic hearing testing application, version 3.309 (hearX group, Pretoria, South Africa). The application is a smartphone-based automated hearing assessment and determines valid and reliable air conduction hearing thresholds at 0.5 kHz – 8 kHz. Automated audiometry began at an intensity of 40dB HL at each frequency, with a minimum intensity of 15dB HL. A threshold was determined as the minimum intensity at which a patient reliably responded twice. The application was operated on a Samsung Trend Neo smartphone (Android OS, 4.0), connected to supra-aural Sennheiser HD280 Pro headphones. The hearTest™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Madsen & Margolis, 2014).

Calibration was performed by means of a G.R.A.S. RA0039 artificial ear using a RION NL-52 sound level meter complying with ISO 60318-1:2009 and ISO 60318-2: 1998 (Van der Aerschot et al., 2016). Background noise recorded by the smartphone was monitored throughout testing and logged along with the test data. These results, in conjunction with otoscopy and tympanometry, were used to identify the presence of a hearing loss. Results collected by the smartphone application were uploaded to a secure cloud-based server via a mobile network for data management.

2.1.6 Procedures for data collection

The procedure for data collection comprised the following procedures.

Community-based hearing screening using the hearScreen™ smartphone application

The subsequent steps were followed during community-based hearing screening:

- CCWs provided informed consent (Appendix C) prior to the commencement of training and data collection. CCWs involved in this study received no formal training in ear and hearing health care. If the care worker agreed to take part in the study, a five hour theoretical and practical training session was held. Training was conducted by the researcher, a qualified audiologist, and included information on general ear and hearing health care, how to administer hearing screenings, and providing relevant follow-up recommendations.
- Following training, CCWs visited homes and community care centres to conduct hearing screenings. Hearing screenings were conducted on community members and their family members (>4 years) who received services from the NPO in Sunnyside.
- Hearing screenings were only conducted if consent/assent had been granted by participants and by parents/guardians of participants <18 years old (refer to Appendix D, E and F).
- CCWs provided each participant with an explanation and demonstration of what the test entailed and what was expected of him/her. The participant was required to raise his/her hand each time they heard the tone presented.
- CCWs were required to enter the participant's identifying information into the smartphone hearScreen™ application. The care worker then placed the headphones on the participant's ears and stood behind the participant to administer the test.
- A conditioning tone was presented first in order to ensure that the participant understood the instructions.
- The smartphone application employs automated test protocols. A sweep was performed at the test frequencies of 1, 2 and 4kHz at an intensity of 25dB HL for children and 35dB HL for adults. The stimulus was repeated once if the participant did not respond at any frequency.
- The smartphone application also makes use of a smart noise-monitoring algorithm. If noise levels exceeded MPANLs, a warning was provided to the CCW who could then move to a quieter room or reduce background noise before continuing the test. Noise levels were automatically recorded by the smartphone application, and testing was completed on the second trial even if noise levels could not be reduced adequately.

- Failure to hear a tone at any frequency in either ear constituted a ‘refer’ result. The participant was then rescreened immediately. In the event that the participant obtained a ‘refer’ result on the rescreen, he/she was referred for a full diagnostic hearing assessment conducted by the researcher within four weeks of the initial screening.
- Results were communicated directly to participants and parents/guardians of participants younger than 18 years old via text message. The text message provided a follow-up date and time at the NPO for a diagnostic hearing assessment.
- Test results collected by the smartphone application were immediately uploaded to a secure cloud-based server via a mobile network for data management.

Diagnostic audiometry follow-up:

The subsequent steps were followed during follow-up diagnostic assessments:

- In the event that the participant obtained a ‘refer’ result on the rescreen, he/she was referred for a full diagnostic hearing assessment.
- The researcher provided a short explanation of what each test entailed and what was expected of the participant prior to testing.
- Once the testing had been completed, results were explained to the participants and to parents/guardians of participants younger than 18 years old. Recommendations and/or referrals for further intervention were made as needed (Appendix G and H).

The researcher carried out a full diagnostic test battery consisting of the following:

- *Otoscopy*

  An otoscopic examination was conducted to determine the condition of the participant’s external ear canal and tympanic membrane (ear drum). Otoscopy was administered in order to identify any possible pathology such as excessive wax, discharge, or perforation of the tympanic membrane.

- *Acoustic immittance measurements*

  Tympanometry was conducted in order to measure the participant's middle ear pressure, volume, and compliance (Katz, 2014). Tympanometry was administered by placing a probe into the participant's ear to determine the presence of any middle ear pathologies.

- *Diagnostic audiometry*

  Automated audiometry consisted of air conduction audiometry at 0.5 kHz – 8 kHz and began at an intensity of 40dB HL at each frequency, with a minimum intensity of 15dB HL. A threshold was determined as the minimum intensity at which a patient reliably responded twice. Calibrated Sennheiser HD280 Pro headphones were placed on the participant. Masking was automatically applied when necessary. The contralateral noise initiated with intensities above 40dB HL. Background noise was monitored throughout testing and was logged into the test data. These results, in conjunction with otoscopy and tympanometry, were used to identify the presence of a hearing loss in terms of type, degree, and possible pathology.

2.1.7 Data analysis

During phase one, data were extracted from the mHealth cloud-based server for statistical analysis. Data were analysed using a statistical software package, SPSS v22 (Chicago, Illinois). A p value of < 0.05 was used as the level of significance. Results were analysed using descriptive statistical measures to describe and synthesize the quantitative data collected regarding the coverage rate of the smartphone hearing screening programme, the referral rate of smartphone hearing screenings, the follow-up rate based on patients who were referred and attended follow-up diagnostic appointments, the compliance of the test environment during hearing screening and diagnostic testing, and time proficiency of smartphone hearing screening and testing. A Chi-square test was also used to determine gender effects on screening results. Frequency distributions and cross-tabulations were used to investigate screening outcomes where MPANLs were exceeded.

2.2 PHASE TWO: CCW knowledge of hearing health and screening experiences

2.2.1 Research aim

Phase two of this research study aimed to describe CCW knowledge of hearing health care and their experiences of the community-based hearing screening programme.

2.2.2 Research design

During this phase, CCW knowledge of hearing health care and experiences of the community-based hearing screening programme were described by employing a survey design based on cross-sectional quantitative questionnaires (Appendix I and J). Both questionnaires used in the current study were adapted from a previous study conducted by Yousuf Hussein et al. (2016) and were self-administered. The first questionnaire consisted of 13 questions using a three-point rating scale (1 indicating yes; 2 indicating unsure; 3 indicating no). The second questionnaire consisted of 10 questions using a five-point Likert rating scale (1 indicating strong agreement; 5 indicating strong disagreement).

2.2.3 Environment

CCWs were invited to complete two short self-administered questionnaires (Appendix I and J). Questionnaires were administered at the NPO in Sunnyside, an area situated just east of the city center of Pretoria, Gauteng Province, South Africa.

2.2.4 Participants

The 15 CCWs utilized in phase one of this research study participated in phase two. All 15 CCWs were literate as well as proficient in English, and could therefore complete the questionnaires in writing.

2.2.5 Materials

During phase two of this research study, CCWs were invited to complete a short self-administered questionnaire regarding their knowledge of hearing health care (Appendix I) following the screening programme. CCWs were also invited to

complete a second self-administered questionnaire regarding their experiences of the community-based screening programme (Appendix J).

The following materials were used during phase two of this research study:

Questionnaire regarding CCW knowledge of hearing health care

The questionnaire used to determine CCW knowledge regarding hearing health care was adapted from a study by Yousuf Hussein et al. (2016). The questionnaire involved general knowledge regarding hearing loss, causes and risk factors associated with hearing loss, identification of hearing loss and intervention as well as attitudes towards hearing loss. The questionnaire consisted of 13 questions using a three-point rating scale (1 indicating yes; 2 indicating unsure; 3 indicating no). The questionnaire was completed anonymously following the programme and took approximately 10 minutes to complete (Appendix I).

Questionnaire regarding CCW experiences of community-based screening programme

The second questionnaire used to describe CCW experiences regarding the community-based screening programme was also adapted from a study by Yousuf Hussein et al. (2016). The questionnaire evaluated perceived usability of ear and hearing health services, value to the community, time proficiency, and involvement in the service provided. The questionnaire consisted of 10 questions using a five-point Likert rating scale (1 indicating strong agreement; 5 indicating strong disagreement), and aimed to determine the clinical efficacy of the community-based hearing screening programme. The questionnaire was completed anonymously and took approximately 10 minutes to complete (Appendix J).

2.2.6 Procedures for data collection

The second phase of this research study evaluated CCWs knowledge of hearing health care and their experiences of the community-based hearing screening programme. CCWs provided informed consent (Appendix C) prior to the commencement of data collection. If the care worker agreed to take part in the study, he/she was invited to complete two short questionnaires.

The following procedures were carried out for data collection:

Questionnaire regarding CCW knowledge of hearing health care

The subsequent steps were followed when administering the first questionnaire:

- Each CCW was invited to complete a self-administered questionnaire adapted from a study by Yousuf Hussein et al. (2016) regarding their knowledge of hearing health care (Appendix I).
- CCWs were invited to complete the questionnaire following the community-based hearing screening programme.
- The questionnaire involved general knowledge, causes and risk factors associated with hearing loss, identification of hearing loss and intervention as well as attitudes towards hearing loss.
- The questionnaire consisted of 13 questions using a three-point rating scale (1 indicating yes; 2 indicating unsure; 3 indicating no).
- The questionnaire was completed anonymously and took approximately 10 minutes to complete.

Questionnaire regarding CCW experiences of community-based screening programme

The subsequent steps were followed when administering the second questionnaire:

- Following the community-based screening programme, each care worker was invited to complete a second self-administered questionnaire adapted from a study by Yousuf Hussein et al. (2016) regarding their experiences of the community-based screening programme (Appendix J).
- The questionnaire involved usability, need for services, value to the community, time proficiency, and their involvement in the service provided.
- The questionnaire consisted of 10 questions using a five-point Likert rating scale (1 indicating strong agreement; 5 indicating strong disagreement).
- The questionnaire was also completed anonymously and took approximately 10 minutes to complete.

2.2.7 Data analysis

In phase two of this research study, responses from the self-administered questionnaires were coded into quantitative data for statistical analysis. The first questionnaire consisted of 13 questions using a three-point rating scale (1 indicating yes; 2 indicating unsure; 3 indicating no). The second questionnaire consisted of 10 questions using a five-point Likert rating scale (1 indicating strong agreement; 5 indicating strong disagreement). Results were analysed using descriptive statistical measures in terms of frequency distribution.

2.3 Ethical considerations

Ethical implications should be considered for all research where human beings are the focus of the research. The National Health Act 61 of 2003 states that research conducted with human beings may only be conducted in the prescribed manner, and with the written consent of the participant after he or she has been informed of the objectives of the research, as well as any possible positive or negative consequences on their health. Where research is to be conducted on a minor, the research may only be conducted if it is in the best interests of the minor and with the consent of the parent or guardian of the child.

The ethical considerations for this research study were as follows:

Informed consent

CCWs invited to participate in this research study, as well as all participants were required to provide written informed consent prior to data collection (Appendix C and D). If the participant was younger than 18 years old, the guardian/parent of the participant was required to provide informed consent and the participants were required to provide assent (Appendix E and Appendix F). Participation in this study was on a voluntary basis. Participants and care workers received written information on what the study entailed as well as their right to withdraw from the study at any time. The information was presented in terminology that the participants understood. In the event that the participant did not understand the information, CCWs assisted in translating the information verbally.

Confidentiality and anonymity

A researcher must respect the privacy of the participants by keeping the nature and quality of the participants' performance strictly confidential (Leedy & Ormrod, 2010). Confidentiality of the participant's identity and personal information was assured throughout the study. The participant's identity was only known by the researcher, and all personal information revealed during the case history interview as well as the results obtained were kept in strict confidence. All data were collected anonymously and stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for research and archiving purposes. Confidentiality of the care workers' answers to the questionnaires was also assured.

Protection from harm

The risk involved in participating in a study should not be greater than the normal risks of day to day living (Leedy & Ormrod, 2010). This research study did not expose the care workers or participants to any physical or emotional harm. Participants benefited from participating in this research study as they received free hearing health care services.

Honesty

All participants were given access to their own test results as well as to the results obtained from the study.

Plagiarism

This research study and written report of the study was the researcher's own original work (appendix K). All secondary material cited was carefully acknowledged and referenced according to APA referencing guidelines. The study adhered to the University of Pretoria policy on plagiarism.

2.4 Reliability and validity

Validity of a measurement instrument refers to the extent to which the instrument measures what it is intended to measure, whereas reliability is the consistency with which a measuring instrument yields a certain result (Leedy & Ormrod, 2010).

Study Phase one

Due to the automated screening system and monitoring of environmental noise levels integrated in the hearScreen™ application, subjective influence of the screening personnel was eliminated during phase one of this research study.

Validity was assessed in terms of:

- Coverage rate of hearing screening programme
- Referral rate of hearing screening programme
- Compliance of the test environment
- Time proficiency of hearing screenings
- Diagnostic follow-up return rate

The reliability of the hearing screenings was assessed in terms of the amount of true referral results obtained.

Study Phase two

The questionnaires used in phase two of this research study were adapted from a previous study conducted by Yousuf Hussein et al. (2016). As these questionnaires were compiled in the previously mentioned study, they were therefore considered reliable and valid. Leedy and Ormrod (2001) define bias as any influence, condition, or set of conditions that may distort the data. Due to the automated screening system integrated in the hearScreen™ application, subjective influence of the screening personnel was eliminated during phase one of this research study. The use of questionnaires in phase two of this research study, however, may have yielded subject bias.

CHAPTER 3

SUPPORTING HEARING HEALTH IN VULNERABLE POPULATIONS THROUGH COMMUNITY CARE WORKERS USING mHEALTH TECHNOLOGIES

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Note: This article was edited in accordance with the editorial specifications of the journal and may differ from the editorial style of the rest of this document.

3.1 Abstract

Objective: Access to ear and hearing care is a challenge in low-to-middle income countries (LMICs) where the burden of hearing loss is greatest. This study investigated a community-based programme for detection and diagnosis of hearing loss, using smartphone hearing screening and testing operated by community care workers (CCWs) in vulnerable populations affected and infected by HIV and AIDS, and to survey the experiences of CCWs providing the service.

Design and Study Sample: The study comprised two phases. In phase one, hearing screening by 15 trained CCWs was administered during home visits using a validated smartphone application (hearScreen™) with calibrated headphones. Diagnostic follow-up assessments included evaluation using the smartphone test (hearTest™), otoscopy and tympanometry. Phase two included a survey on CCW's knowledge on hearing health and experiences of the hearing screening programme.

Results: 276 adults (mean 30.4; SD 9.1) and 235 children (mean 8.7; SD 4.1) were tested over an eight-week period. Referral rates for adults and children were 5.0%

and 4.2% respectively. 75.0% of referred participants returned for follow-up diagnostic assessments, 33.3% were diagnosed with hearing difficulties and referred for further intervention services. All CCWs agreed that community members needed hearing health services and only 6.6% did not want to provide hearing testing as part of their services.

Conclusion: Simple smartphone-based hearing testing allows minimally trained CCWs to decentralize hearing services to vulnerable populations in communities. Active noise monitoring and remote data management features allow for quality control and telehealth surveillance.

3.2 Introduction

Hearing loss is one of the most frequently occurring non-fatal disabling conditions, affecting individuals, communities and societies worldwide (WHO, 2018). In 2015, approximately half a billion people worldwide were living with a disabling hearing loss, approximately 6 to 8% of the world's population (Wilson et al., 2017). The prevalence of hearing loss is substantially higher in low-to-middle income countries (LMICs) such as in sub-Saharan Africa, which accounts for 9% of hearing loss globally (WHO, 2018; WHO, 2012). Studies have demonstrated that even a mild hearing loss, if unidentified, can affect a child's speech and language development, and ultimately can exert a negative impact on their behavior, education and overall well-being (Wenjin et al., 2014). In developing countries where illiteracy levels are high and spoken communication is predominantly used, the effects of a disabling hearing loss can be even more adverse and detrimental (Swanepoel et al., 2010a). Unfortunately, the majority of such populations live in communities where hearing health care services are inaccessible or severely limited (Mulwafu et al., 2017).

The substantial burden of hearing loss and inadequate access to ear and hearing health care in developing countries necessitate new and improved methods of providing access to services (Yousuf Hussein et al., 2016). Unfortunately the number of hearing health providers is precariously insufficient in developing countries, with estimates of only one audiologist per 0.5 million to 6.25 million people in developing countries worldwide; less than one audiologist for every one million people in sub-Saharan Africa (Goulios & Patuzzi, 2008; Mulwafu et al., 2017; Windmill & Freeman,

2013). Ultimately innovative approaches are required to increase access for both children and adults to hearing health services.

Furthermore, many LMICs are also affected by the HIV and AIDS pandemic and experience serious health, social and economic consequences (Andrews et al., 2006). Subsequently this exacerbates the already limited access to good quality ear and hearing health services for vulnerable populations, due to additional costs associated with conventional hearing services (Mulwafu et al., 2017). At the end of 2015, approximately 36.7 million people worldwide (0.05% of the global population) were infected with HIV and AIDS, with the vast majority of these people living in low-to-middle income households in sub-Saharan Africa (WHO, 2017). Thus this communicable disease remains one of the primary causes of adult and child mortality in developing countries (Ssengonzi, 2009). With a generation of children already orphaned with the loss of one or both parents due to HIV and AIDS, the traditional family structure is often no longer in place and many grandparents are left to provide care and support to vulnerable populations (Andrews et al., 2006). The prevalence of chronic otitis media as well as conductive and sensorineural hearing loss is typically high among HIV-infected children (Ensink & Kuper, 2017; Ndoleriire et al., 2013), especially among advanced stages of HIV (Swanepoel et al., 2010a; Torre et al., 2012). The HIV and AIDS epidemic and associated increased prevalence of hearing loss necessitate new and improved service-delivery models to ensure access to preventative ear and hearing health services.

Evidence suggests that primary health care visits may be the only platform where ear and hearing health services could be accessed by individuals with hearing loss in LMICs (Bogardus et al., 2003). Unfortunately many barriers exist to accessing these services within primary health care settings. One apparent barrier is the cost, both in terms of time and resources, attending clinics, as well as high costs associated with conventional screening and diagnostic audiometric equipment (Swanepoel et al., 2010a). Furthermore, there are limited hearing health professionals available in these settings who can offer the services (Swanepoel et al., 2010a). Ultimately this highlights the need for a decentralised community-based approach to ensure support within vulnerable households.

The use of telehealth approaches have been proposed as one way in which access to care could be improved and existing barriers overcome (Swanepoel et al., 2010a; Swanepoel et al., 2010b). It offers unique opportunities in providing access to hearing health services, such as mobile health (mHealth) using smartphones among other portable devices (Clark & Swanepoel, 2014; Davis & Smith, 2013). Smartphone hearing testing using the hearScreen™ application has been demonstrated to be valid and appropriate for use in primary health care and community-based settings (Mahomed-Asmail et al., 2016; Sandstrom et al., 2016; Swanepoel et al., 2014; Van Tonder et al., 2017). Smartphone hearing testing offers an inexpensive and mobile alternative to conventional hearing screening, which utilizes widely available smartphone and headphone technology and provides time-efficient identification of hearing loss (Louw et al., 2017). No significant difference between test results obtained via conventional behavioural hearing screening as compared to smartphone hearing screening has been reported, with no substantial difference among sensitivity and specificity rates (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014). Furthermore, quality control measures are integrated into these smartphone solutions to monitor environmental noise levels, test operator performance and also simplify data management referrals and reporting (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014).

These types of mHealth solutions employ simple user-interfaces and automated test sequences that allow minimally trained laypersons such as community care workers (CCWs) to render services in communities (Yousuf Hussein et al., 2018; Yousuf Hussein et al., 2016; UNESCO, 2017). CCWs provide various services for disadvantaged households and allow hearing health care services to be brought to underserved communities at a primary care level (Yousuf Hussein et al., 2016). By directly visiting households, CCWs improve the accessibility of health services and can ultimately reduce the costs involved (Braun, 2013). By shifting tasks from highly trained personnel to community members, the demands placed on limited ear and hearing health professionals in LMICs are also reduced (Chadha, 2013; Yousuf Hussein et al., 2016).

The potential applications and possible impact of mHealth solutions facilitated by CCWs in communities are significant. Employing a decentralized approach to

service-delivery (Chadha, 2013), mHealth may provide a cost-effective and sustainable means of providing ear and hearing health services to households in LMICs, ensuring timely referral and follow-up. The current study therefore investigated a community-based programme supporting vulnerable populations affected and infected by HIV and AIDS to identify hearing loss using smartphone screening operated by CCWs linked to a cloud-based data management system. A secondary objective was to describe CCW knowledge and user experience of the service.

3.3 Materials and Methods

Institutional review board clearance was obtained before any data collection commenced. The study included two phases. The first phase evaluated mHealth community-based hearing detection and diagnosis of children and adults affected and/or infected by HIV and AIDS. The second phase described CCW knowledge of hearing health and experiences of the community-based hearing screening programme.

3.3.1 Phase 1: Community-based Hearing Detection and Diagnosis

Participants

Participants were selected from a LMIC community in the City of Pretoria, Gauteng Province, South Africa. Convenience sampling was employed to invite CCWs to be trained for inclusion of behavioral pure tone hearing screenings to their home-based services. 15 CCWs agreed to take part in the current study. These CCWs were recruited from local communities within Pretoria by a non-profit organization (NPO) situated in Pretoria, South Africa, to provide various services to disadvantaged households. Each CCW was assigned to 20 households and offered hearing screenings as an additional service during home-based visits within Pretoria.

Non-probability purposive sampling was used to invite approximately 500 individuals who previously received services from CCWs as part of the NPO's initiative to participate in this study. Participants included adults and children (>4 years old) infected or who have family members infected with HIV and AIDS who reside in Pretoria.

Material and Apparatus

Hearing screening was conducted using the hearScreen™ application, version 3.309 (hearX group, Pretoria, South Africa), installed on six Samsung Trend Neo smartphones (Android OS, 4.0) connected to supra-aural Sennheiser HD280 Pro headphones. The hearScreen™ calibration function was used to calibrate the headphones according to prescribed standards (ISO 389-1:1998) adhering to equivalent threshold sound pressure levels determined for this headphone according to ISO 389-9:2009 (Madsen & Margolis, 2014). Calibration was performed using a G.R.A.S. RA0039 artificial ear using a RION NL-52 sound level meter complying with ISO 60318-1:2009 and ISO 60318-2: 1998 (Van der Aerschot et al., 2016). The hearScreen™ application employs automated test protocols (Figure 1). A sweep test was performed at the test frequencies of 1, 2 and 4kHz at an intensity of 25dB HL for children and 35dB HL for adults. Noise levels are recorded and monitored by the smartphone application to avoid exceeding maximum permissible ambient noise levels (MPANLs) during testing. A quality index (QI) is recorded, which indicates the quality of tests conducted by the test operator by reflecting the number of false-positive responses obtained by the test operator when a non-stimulus condition is randomly presented to the participant.

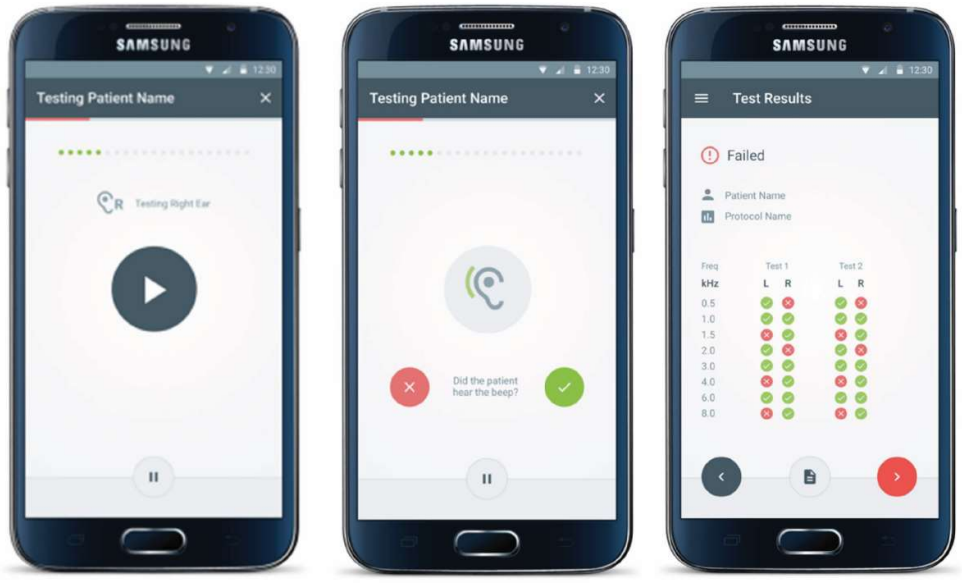

Figure 1: hearScreen™ user-interface for (a) stimulus presentation, (b) response options, and (c) results page.

Diagnostic assessments included diagnostic audiometry using the hearTest™ smartphone application, version 3.309 (hearX group, Pretoria, South Africa), otoscopy and tympanometry (Katz, 2014) which were conducted using a Welch Allyn otoscope and a GSI 38 Auto Tympanometer. The hearTest™ mobile diagnostic testing application, version 3.309 (hearX group, Pretoria, South Africa), was installed on one Samsung Trend Neo smartphone (Android OS. 4.0) and utilized for air conduction threshold pure tone audiometry (Sandstrom et al., 2016; Van Tonder et al., 2017). This application is a self-administered, automated hearing assessment that has been validated to record reliable air conduction hearing thresholds (Van Tonder et al., 2017). Automated audiometry consisted of air conduction testing at 0.5 to 8 kHz starting at an intensity level of 40dB HL until a minimum response level of 10dB. The threshold determination sequence follows the Threshold Ascending method as specified in ISO 82531:1.5. Noise levels were recorded and monitored by the smartphone application to avoid exceeding MPANLs.

Procedures

Smartphone hearing screening. Hearing screenings were conducted by 15 CCWs who provided consent to participate in the study. CCWs involved in this study had no formal training in ear and hearing health care. A five-hour training session was conducted, by the first author, prior to the implementation of the screening programme. The CCWs were trained in general ear and hearing health care, how to administer smartphone hearing screenings and were given a practical session for hands-on experience. Hearing screenings were only conducted if consent/assent had been granted by participants and parents/guardians of participants younger than 18 years of age. Each participant was provided with a simple explanation and demonstration of what the test entails and what is expected of him/her. A CCW, seated behind each participant, instructed participants to raise their hand each time they heard the tone presented. A conditioning tone was presented first in order to ensure that the participant understood the instructions.

The hearScreen™ application makes use of a smart noise-monitoring algorithm. If noise levels exceeded MPANLs; a warning was provided to the CCW who could then move to a quieter room or reduce background noise before continuing the test. Noise levels were automatically recorded by the smartphone application, and testing was

completed on the second trial even if noise levels could not be reduced adequately. Once the test was complete, the hearScreen™ application immediately calculated and displayed to the CCW the results at each frequency and an overall “pass” or “refer” result. A random non-presentation of the stimulus is initiated during testing as a test operator QI. If the test operator indicates that the participant heard this stimulus it is flagged as a false-positive response by the operator. This QI score is monitored and a score below 70% is flagged for retraining.

Failure to hear a tone at any frequency in either ear constituted a ‘refer’ result and an immediate rescreen was conducted. If the participant referred the rescreen; he/she was referred for a full diagnostic hearing assessment conducted by the researcher within four weeks. Results were communicated directly via text messages to participants and/or parents/guardians of participants younger than 18 years of age. Test results collected by the smartphone application were immediately uploaded to a secure cloud-based server via a mobile network for data management.

Diagnostic follow-up. Diagnostic testing was conducted by the first author within four weeks of the initial screening at the NPO’s office in Pretoria. Participants were provided with a short explanation of what each test entails and what is expected of him/her. Testing comprised otoscopy, tympanometry and air conduction threshold audiometry using the hearTest™ application to determine degree and configuration. Testing mode was differentiated between manual and automated depending on the participant’s age and ability to use the response button on the device. In the event the participant was unable to respond or hold the device themselves; a test-operator mode was enabled to permit manual testing by the first author.

Background noise recorded by the smartphone was monitored throughout testing. A threshold was determined by the minimum intensity at which the participant reliably responded twice. These results, in conjunction with otoscopy and tympanometry, were used to identify the presence of a hearing loss. Results collected by the smartphone application were uploaded to a secure cloud-based server via a mobile network for data management. Once diagnostic testing was completed, if needed participants were referred to their closest tertiary hospital that offered the required medical or audiological services.

Data analysis

Data were extracted from the cloud-based server to an MS Excel spread-sheet for statistical analysis. Results were analysed using descriptive statistics to analyse coverage rate, referral rate, follow-up rate, compliance of the test environment and time proficiency of the hearing screenings. A p value of < 0.05 was used to indicate the level of significance using the Pearson Chi-Square test.

3.3.2 Phase 2: CCW Knowledge of Hearing Health and Screening Experiences

Participants

The 15 CCWs invited to conduct hearing screenings during phase one were invited to report on their knowledge and experiences of community-based hearing screening programme in terms of perceived usability, need for services, value to the community, time proficiency and their involvement in the service provided by means of a second questionnaire.

Material and Apparatus

CCWs were invited to complete two self-administered questionnaires. The first questionnaire consisted of 13 questions using a three-point rating scale (1 indicating yes; 2 indicating unsure; 3 indicating no) regarding their knowledge of hearing health care. The second questionnaire was adapted from a previous study and consisted of 10 questions to be answered using a five-point Likert rating scale of 1 indicating strong agreement; 5 indicating strong disagreement (Yousuf Hussein et al., 2016). The second questionnaire surveyed usability, need for services, value to the community, time proficiency and their involvement in the service provided.

Procedures

The two self-administered questionnaires were completed at the NPO's office in Pretoria. CCWs were invited to complete two self-administered questionnaires following the community-based hearing screening programme. Both questionnaires were completed anonymously and took approximately 10 minutes to complete.

Data analysis

Responses from the questionnaires were coded into quantitative data in MS Excel for statistical analysis. Results were analysed using descriptive statistical measures in terms of frequency distribution.

3.4 Results

3.4.1 Phase 1: Community-based Hearing Detection and Diagnosis

A total of 511 participants, including 276 adults (mean 30.4; SD 9.1) and 235 children (mean 8.7; SD 4.1) were included in this study over a period of eight weeks. Of the 511 participants screened; 61.0% (n = 312) were female and 38.9% (n = 199) were male. Mean test duration recorded for initial screenings, excluding time taken for instructions and capturing of demographic information, was 73.5 seconds (SD 49.9) for children, and 57.9 seconds (SD 37.9) for adults. A total of 30 adults (10.8%) and 31 children (13.1%) failed the initial screening and were automatically rescreened (Table 1). The average age for individuals who initially referred the screening was 9.3 years (range 2-15 years; SD 4.95) for children, and 34.7 years (range 19-66 years; SD 10.6) for adults. Age demonstrated no significant effect on the initial screening referral rate in adults ($p > 0.05$; Pearson chi-square). Although more female (13%; n = 40) than male (11%; n = 21) participants (adults and children) failed the initial screen, the difference was not significant ($p > 0.05$; Pearson chi-square).

Table1. Referral rates for screening in children and adults using the smartphone hearing test.

	Adults (n = 276)		Children (n = 235)	
	(n)	(%)	(n)	(%)
Initial screen				
Left 1kHz	11	4.0	14	6.0
Left 2kHz	8	2.9	14	6.0
Left 4kHz	12	4.3	8	3.4
Right 1kHz	10	3.6	12	5.1
Right 2kHz	8	2.9	9	3.8
Right 4kHz	11	4.0	9	3.8
Overall initial screen	**30**	**10.8**	**31**	**13.1**
Immediate rescreen				
Left 1kHz	4	1.4	2	0.9
Left 2kHz	3	1.1	3	1.3
Left 4kHz	6	2.2	3	1.3
Right 1kHz	6	2.2	5	2.1
Right 2kHz	4	1.4	4	1.7
Right 4kHz	6	2.2	4	1.7
Overall rescreen	**14**	**5.0**	**10**	**4.2**

The average age for individuals who referred the rescreen was 9.6 years (range 2-15 years; SD 5.4) for children, and 34.2 years (range 19-46 years; SD 10.6) for adults. The overall referral rate decreased from 10.8% to 5.0% (n = 14) for adults, and 13.1% to 4.2% (n = 10) for children following rescreening after an initial refer result.

A QI of less than 70% for conducting the hearing screening was obtained by 46.6% (mean = 49.5%; SD 34.8) of CCWs indicative of retraining required. MPANLs were exceeded at 1 kHz in the left ear in 1.6% and 6.1% of adults and children respectively, and in the right ear in 1.2% and 7.8% of adults and children respectively. However, exceeded noise levels demonstrated no significant effect on the initial screen and rescreen outcomes in both children and adults ($p>0.05$; Pearson chi-square). Mean test duration for children was 73.5 seconds (SD 49.9), and 57.9 seconds (SD 37.9) for adults.

A total of 24 (4.6%) participants (range 6-46 years; 14 adults and 10 children) were referred for diagnostic audiometry of whom 18 (75.0%) returned for the follow-up assessment. Mean threshold audiometry (hearTest™) test duration was 672.75 seconds (SD 304.3) for children, and 452.1 seconds (SD 202.2) for adults. No MPANLs were exceeded at any frequency. Six (33.3%) referred participants (n = 6) were confirmed to have hearing loss (Table 2) and referred for further intervention.

Table 2. Description of referred participants (n = 6).

Age	Gender	Hearing Loss Configuration
30	Female	Bilateral moderate-to-severe SNHL
33	Female	Unilateral severe-to-profound SNHL
38	Female	Bilateral moderate-to-severe SNHL
12	Female	Bilateral mild SNHL
46	Male	Bilateral mild SNHL
6	Male	Bilateral mild CHL

3.4.2 Phase 2: CCW Knowledge of Hearing Health and Screening Experiences

Following the screening programme, all CCWs (100%; n = 15) were of the opinion that community members needed hearing health services since healthy hearing is important within the community (Table 3). 93.3% of CCWs also indicated that hearing loss may affect more individuals than others (Table 3), and 46.6% of CCWs were of the opinion that children with a hearing loss are more likely to perform poorer academically as compared to normal hearing peers (Table 3).

Table 3. Survey of CCWs (n = 15) responses (%) regarding knowledge of hearing health.

Questions	Yes	Unsure	No
1. Worked with someone with a hearing loss?	33.3	6.6	60.0
2. Community needs hearing health?	100.0	-	-
3. Can hearing loss be congenital?	93.3	6.6	-
4. Illness cause hearing loss?	86.6	13.3	-
5. Affect some people more than others?	93.3	6.6	-
6. Hearing loss identified at any age?	60.0	20.0	20.0
7. Hearing loss can be treated?	60.0	40.0	-
8. Children with hearing loss do well?	20.0	33.3	46.6
9. Impact listening in classroom?	80.0	6.6	13.3
10. Impact speech and language?	66.6	26.6	6.6
11. Impact work?	66.6	20.0	13.3
12. Impact social interactions?	73.3	13.3	13.3
13. Would like information on hearing loss?	93.3	6.6	-

86.6% of CCWs (n = 13) agreed or strongly agreed that hearing screening was quick and easy to administer in adults whilst only 66.6% (n = 10) agreed or strongly agreed that it was easy to administer in children (Table 4). The majority (60.0%) of CCWs agreed or strongly agreed that community members were positive about receiving this service. Most (60.0%) CCWs strongly agreed or agreed in continuing providing hearing screening as part of their services and only one (6.6%) disagreed (Table 4).

Table 4. Distribution of CCWs (n = 15) responses (%) on experiences of screening programme.

Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Instructions straightforward	66.6	26.6	6.6	-	-
2. Administration easy (adults)	40.0	46.6	-	6.6	6.6
3. Administration easy (children)	6.6	60.0	20.0	6.6	6.6
4. Administration quick	46.6	33.3	13.3	-	6.6
5. Community needs hearing health	60.0	33.3	6.6	-	-
6. Community positive about service	13.3	46.6	40.0	-	-
7. Community trusts results	20.0	40.0	26.6	13.3	-
8. CCW trusts results	20.0	46.6	26.6	6.6	-
9. Important for community	40.0	53.3	6.6	-	-
10. CCW would continue service	33.3	26.6	33.3	6.6	-

3.5 Discussion

There is limited research on community-based programmes for detection and diagnosis of hearing loss, particularly within vulnerable populations in sub-Saharan Africa (Chadha, 2013; Yousuf Hussein et al., 2016). This study is the first report on a mHealth assisted hearing detection and diagnosis programme within a vulnerable community using minimally trained CCWs. The use of mHealth solutions operated by CCWs is a novel approach to improve access to hearing health services within under-resourced communities (UNESCO, 2017; Yousuf Hussein et al., 2018; Yousuf Hussein et al., 2016). Fifteen CCWs screened a total of 511 community members (235 children; 276 adults) within an eight-week period during regular home-based visits. The majority of community members screened were adults (n = 276), of which

majority were female 68.8% (n = 190). This may be due to the home-based visits taking place in the week during work hours (Yousuf Hussein et al., 2016).

The initial referral rate in children (range 2-18 years) and adults (range 19-70 years) decreased from 13.1% and 10.8% to 4.2% and 5.0% respectively following the immediate rescreen, which forms part of the screening protocol (AAA, 2011). Rescreens have been reported to decrease the referral rate in children by half, and are therefore recommended directly after initial screening refers in order to decrease the number of possible false-positive results (AAA, 2011). Higher initial referral rates prior to rescreening can likely be due to a poor understanding of instructions (Yousuf Hussein et al., 2016). CCWs were prompted by the application to reduce noise levels before rescreening as far as possible. Although MPANLs were exceeded at one frequency in some cases (left ears: 1.6% cases; right ears: 1.2% cases); no statistically significant effect ($p>0.05$; Chi-square) of MPANLs was observed on screening outcomes. Age also demonstrated no significant effect on the initial and overall referral rate in adults ($p>0.05$; Chi-square). A previous study reported a referral rate of 4.3% for children (Swanepoel et al., 2014); which is in line with the referral rate of children (4.2%) in the current study. Another recent study reported a referral rate of 12% for children aged 2-15 using the hearScreen™ smartphone application (Yousuf Hussein et al., 2016). Lower referral rates (4.2%) for children in the current study are likely due to lower environmental noise levels than in the previous study.

Average test duration for initial smartphone hearing screening, excluding time taken for instructions and capturing of demographic information, was 73.5 seconds (SD 49.9) for children; slightly longer in comparison to previous studies which obtained an average of 54.5 seconds (SD 28.3) and 47.4 seconds (SD 20.0) when screening children (Mahomed-Asmail et al., 2016; Yousuf Hussein et al., 2016). The current study obtained an average test duration of less than a minute when screening adults (57.9 s; SD 37.9); similar to that of a previous study which obtained 47.0 seconds (SD 28.8) when screening adults initially (Yousuf Hussein et al., 2016). In comparison to conventional hearing screening, other studies reported an average time of more than two minutes for children; considerably longer than smartphone-based screening (Liew et al., 2009; Wenjin et al., 2014). Shorter test time in the

current study may be attributed to the automated screening protocol, compared to manual conventional screening (Mahomed-Asmail et al., 2014). Time efficiency with the smartphone hearing screening application may facilitate screening of larger numbers of individuals over a shorter period of time. 46.6% of CCWs obtained a QI of less than 70% (mean = 49.5%; SD 34.8) when conducting the hearing screenings initially, which signalled the need for retraining. Following retraining, CCWs obtained the required QI and could then continue providing hearing screenings. Further developments to the software are recommended to include a timeframe of the QI at certain intervals throughout a testing period in order to monitor progression following retraining.

A total of 24 participants (14 adults; 10 children) out of the 511 participants screened were referred for diagnostic audiometry via text message. Text messaging has been found to be an effective strategy in increasing follow-up return rate (Liew et al., 2009). Two out of three (18/24; 75%) participants returned for diagnostic follow-up assessments indicating an acceptable follow-up return rate. A 70% and higher follow-up return rate is considered a benchmark (JCIH, 2007). Failure to attend follow-up appointments is likely due to diagnostic assessments taking place in the week during work hours, or barriers associated with traveling such as distance and costs involved (Jones et al., 2005; Yousuf Hussein et al., 2016). Increase in community awareness on the importance of ear and hearing health care, especially within vulnerable communities, may further motivate referred participants to pursue follow-up services.

Average test duration for the diagnostic smartphone application (hearTest™) conducted for follow-up appointments, was 11.21 minutes (672.75 s, SD 304.3) for children and 7.53 minutes (452.1 s, SD 202.2) for adults (excluding instructions). A previous study reported a mean test duration of 6.75 minutes (SD 1.5) when testing adults using the hearTest™ application, similar to that of the current study (Van Tonder et al., 2017). Longer testing times for children in the current study are likely attributed to difficulties with instructions and possible listening fatigue. Listening fatigue may be experienced in children whose hearing is within normal limits, and more commonly in children with hearing loss (Hicks & Tharpe, 2002). A total of 6 participants were identified with hearing loss and referred for further intervention.

Due to the high prevalence of hearing loss within vulnerable communities, access to ear and hearing services is important (Ndoleriire et al., 2013; Smith et al., 2017). Using CCWs supports a decentralised model to create access (Yousuf Hussein et al., 2018; Yousuf Hussein et al., 2016). In this study CCWs reported that the community was positive about receiving hearing services in their home environments with the majority of CCWs indicating that it was quick and easy to administer in adults (86.6%) and children (66.6%). In a previous study, CHWs also identified screening children as an area in which they required additional experience (Yousuf Hussein et al., 2016). CCWs may therefore benefit from further information and training to ensure quality control and confidence when testing children.

3.6 Conclusion

CCWs can be trained to screen for hearing loss during home-based visits in LMIC communities in a timely and affordable manner using smartphone technologies linked to a cloud-based data management system for remote monitoring and referral. These mHealth approaches, using minimally trained community members, can decentralize access to hearing health services within communities, reducing the demands placed on limited ear and hearing health professionals (Yousuf Hussein et al., 2016). Integrated quality control measures for environmental noise and test operators allows for remote surveillance within an integrated data management platform. CCWs were positive towards smartphone hearing screening for vulnerable populations and wanted to continue the service as part of their regular home-based services. mHealth solutions can provide a simple, cost-effective and sustainable means of providing access to ear and hearing health care to vulnerable households in LMICs using minimally trained community members.

CHAPTER 4
DISCUSSION, CLINICAL IMPLICATIONS AND CONCLUSION

Empowering underserved communities through the use of mHealth solutions is a novel approach presenting promising opportunities for improved access to primary care services such as ear and hearing health care (Braun et al., 2013). To date, there has been a shortage of research evidence available on community-based programmes for detection and diagnosis of hearing loss, particularly within vulnerable communities in LMICs such as within sub-Saharan Africa where hearing loss is common (Chadha, 2013; Yousuf Hussein et al., 2016). Contextual evidence and strategies are therefore a necessity when implementing effective programmes aimed at improving access to and awareness of hearing health care services within vulnerable communities.

This study was conceptualized to evaluate the clinical efficacy of a community-based hearing detection and diagnosis programme facilitated by minimally trained CCWs within a LMIC context for vulnerable populations using mHealth solutions (Swanepoel et al., 2014). The aim of this chapter is to draw general conclusions, to suggest implications, and to critically evaluate the mHealth community-based hearing detection and diagnosis programme. Recommendations regarding a proposed community-based screening programme and future research are also made.

4.1 Discussion of results

4.1.1 Phase one: Evaluating mHealth community-based hearing detection and diagnosis

The main study findings are summarised below according to coverage rate, referral rate, reliability of hearing screenings conducted, compliance of the test environment, time proficiency of hearing screening, and diagnostic follow-up return rate.

Coverage rate

Fifteen CCWs conducted community-based hearing screenings over a period of eight weeks during which 511 community members (235 children; 276 adults) were screened. The majority of community members screened were adults (n = 276), of whom 68.8% (n = 190) were female. The greater percentage of female adults screened is most likely due to households being visited within working hours during the week (Yousuf Hussein et al., 2016).

Referral rate

Referral rates were analysed and compared to rates reported in other studies in order to evaluate the mHealth community-based hearing detection and diagnosis programme. The initial referral rate found in children (range 2-18 years) using the hearScreen™ application was 13.1%. After an immediate rescreen referral rates dropped to 4.2%. The initial referral rate obtained in adults (range 19-70 years) also decreased from 10.8% to 5.0% following the immediate rescreen. Rescreens have been reported to decrease the referral rate in children by half, and are therefore recommended directly after initial screening refers in order to decrease the number of possible false-positive results (AAA, 2011). It is likely that the higher initial referral rates prior to rescreening can be attributed to a poor understanding of instructions (Yousuf Hussein et al., 2016). Age also demonstrated no significant effect on the initial and overall referral rate in adults and children ($p>0.05$; Chi-square).

A previous study reported a referral rate of 4.3% for children (Swanepoel et al., 2014); which is in line with the referral rate of children (4.2%) in the current study. A recent study reported a referral rate of 12% for children aged 2-15 using the hearScreen™ smartphone application (Yousuf Hussein et al., 2016). Lower referral rates (4.2%) for children in the current study are possibly due to younger children (<4 years of age) being included in the previous study as well as lower environmental noise levels in the current study.

Reliability of screenings conducted

46.6% of CCWs obtained a QI of less than 70% (mean = 49.5%; SD 34.8) when conducting the hearing screenings initially, which indicated the need for retraining. Further developments to the software are recommended to display any

improvements to a test operator's QI throughout a testing period in order to monitor progression following retraining.

Compliance of test environment

Environmental noise poses a challenge to the successful implementation of hearing screening programmes within uncontrolled environments, such as home visits and schools (AAA, 2011). Therefore it is imperative that noise levels are monitored throughout testing, as in the case of the present study. CCWs were prompted by the application to reduce noise levels before rescreening as far as possible. Although MPANLs were exceeded at one frequency in some cases (left ears: 1.6% cases; right ears: 1.2% cases), no statistically significant effect ($p>0.05$; Chi-square) of MPANLs on screening outcomes was observed.

Time proficiency

Average test duration for initial smartphone hearing screening, excluding time taken for instructions and capturing of demographic information, was 73.5 seconds (SD 49.9) for children; slightly longer in comparison to previous studies which obtained an average of 54.5 seconds (SD 28.3) and 47.4 seconds (SD 20.0) when screening children (Mahomed-Asmail et al. 2016; Yousuf Hussein et al. 2016). Longer testing times for children in the current study can most likely be attributed to difficulties with instructions. An average test duration of less than a minute was obtained when screening adults in the current study (57.9 s; SD 37.9), similar to that of a previous study which obtained 47.0 seconds (SD 28.8) when screening adults initially (Yousuf Hussein et al., 2016). In comparison to conventional hearing screening, studies have reported an average time of more than two minutes for children, considerably longer than for smartphone-based screening (Liew et al., 2009; Wenjin et al., 2014). Shorter test time in the current study may be attributed to the automated screening protocol, compared to manual conventional screening (Mahomed-Asmail et al., 2014). Time efficiency with the smartphone hearing screening application may facilitate screening of larger numbers of individuals over a shorter period of time.

Diagnostic follow-up

Data were uploaded to a secure cloud-based server via a mobile network for remote monitoring and data management. A total of 24 community members (14 adults; 10

children) failed the immediate rescreen and were referred via text message for a full diagnostic hearing assessment. Text messaging has been found to be an effective strategy in increasing follow-up return rate (Liew et al., 2009). Out of the 24 participants referred for diagnostic audiometry; 75% of participants (18/24) returned for diagnostic follow-up assessments indicating an acceptable follow-up return rate. A 70% and higher follow-up return rate is considered a benchmark (JCIH, 2007). A total of 6 participants (6/18; 33.3%) were identified with hearing loss and referred for further intervention. Failure to attend follow-up appointments is most likely due to diagnostic assessments taking place in the week during work hours, or barriers associated with traveling such as distance and costs involved (Jones, Sherman & Varga, 2005; Yousuf Hussein et al., 2016). Increased community awareness with regard to the importance of ear and hearing health care, especially within vulnerable communities, may further motivate referred participants to pursue follow-up services.

Follow-up diagnostic hearing assessments consisted of otoscopy, acoustic immittance measurements, and diagnostic audiometry using the diagnostic smartphone application (hearTest™). Average test duration for the diagnostic smartphone application (hearTest™) was 11.21 minutes (672.75 s, SD 304.3) for children and 7.53 minutes (452.1 s, SD 202.2) for adults (excluding instructions). A previous study reported a mean test duration of 6.75 minutes (SD 1.5) when testing adults using the hearTest™ application, similar to that of the current study (Van Tonder et al., 2017). Longer testing times for children in the current study can most likely be attributed to difficulties with instructions and possibly listening fatigue. Listening fatigue may be experienced in children whose hearing is within normal limits, and more commonly in children with hearing loss (Hicks & Tharpe, 2002). A total of 6 participants were identified with hearing loss and referred for further intervention.

4.1.2 CCW knowledge of hearing health and screening experiences

CCWs had a positive attitude towards smartphone hearing screening for vulnerable populations, and wanted to continue providing the service as part of their regular home-based services. CCWs also reported that the community was positive about receiving hearing services in their home environments, with the majority of CCWs indicating that it was quick and easy to administer in adults (86.6%) and children

(66.6%). In a previous study, CHWs also identified screening children as an area in which they required additional experience (Yousuf Hussein et al., 2016). CCWs may therefore benefit from further information and training to ensure quality control and confidence when testing children.

4.2 Clinical implications and recommendations

Results from this study demonstrate that CCWs can be trained to successfully screen for hearing loss using smartphone technologies, allowing for more cost-effective and timely decentralised hearing health care services. However, findings from this study also demonstrate that such services may require expansion and improvements in specific areas to ensure quality of these services, as well as sustainability over time. These areas are described below.

CCWs providing services

The employment of CCWs integrated with mHealth screening initiatives can improve access to hearing health care services for individuals for whom services are not readily available within a community-based setting. By shifting tasks from highly trained personnel to community care workers; the demands placed on limited ear and hearing health professionals are reduced (Chadha, 2013; Yousuf Hussein et al., 2016). CCWs may therefore be vital co-workers in addressing the shortage of hearing health care professionals. Findings from the hearing screening programme and questionnaires indicated that CCWs could successfully screen for hearing loss using the hearScreen™ application. CCWs may, however, benefit from further information and multiple ongoing training sessions in order to ensure quality of tests as measured by the QI, as well as confidence when testing children.

mHealth smartphone-based tools

Results from this study demonstrate that the use of mHealth solutions can be utilized to successfully screen for hearing loss within a community-based setting. Smartphone hearing testing offers an inexpensive and mobile alternative to conventional hearing screening, thereby offering time-efficient, cost-effective and decentralised detection of hearing loss (Louw et al., 2017). Furthermore, an added benefit of using mHealth tools for hearing screening is that it allows monitoring of environmental noise levels and test operator performance, as well as data capturing

and sharing on site (Mahomed-Asmail et al., 2016; Swanepoel et al., 2014). Guidelines and informational counselling may be beneficial if integrated into the hearScreen™ application in order to better equip CCWs (Yousuf Hussein et al., 2016). Further developments to the software are also recommended to display improvements to a test operator's QI throughout a testing period in order to monitor progression following retraining.

Proposed community-based hearing screening programme

A proposed model for a community-based hearing screening programme is indicated in Figure 2 and described below.

The proposed model was designed based on the clinical implications and recommendations mentioned above. As audiologists are rarely based at primary health care clinics, an audiologist based at a district/tertiary hospital could serve as a programme manager within that area. Duties of the programme manager would include training of CCWs from local NPOs, ensuring all equipment is calibrated, ongoing support and monitoring of the programme as well as providing follow-up diagnostic assessments and intervention services if needed.

Following training, CCWs will provide hearing screening as part of their regular services during home-based visits. The smartphone application employs automated test protocols where a sweep should be performed at the test frequencies of 1, 2, and 4kHz at an intensity of 25dB HL for children and 35dB HL for adults. Failure to hear a tone at any frequency in either ear constitutes a 'refer' result. The community member will then be rescreened immediately. In the event that the community member obtains a 'refer' result on the rescreen; he/she will be referred to the programme manager at the closest district/tertiary hospital for further diagnostic assessments and intervention services. CCWs should also provide community members with informational counselling.

Monthly meetings with CCWs should also take place at each district/tertiary hospital in order to follow-up on individuals who referred the screening and require further diagnostic assessments and/or intervention services. In conjunction with monthly

meetings, data collected by the smartphone application should also be reviewed in order to ensure a sustainable and effective screening programme.

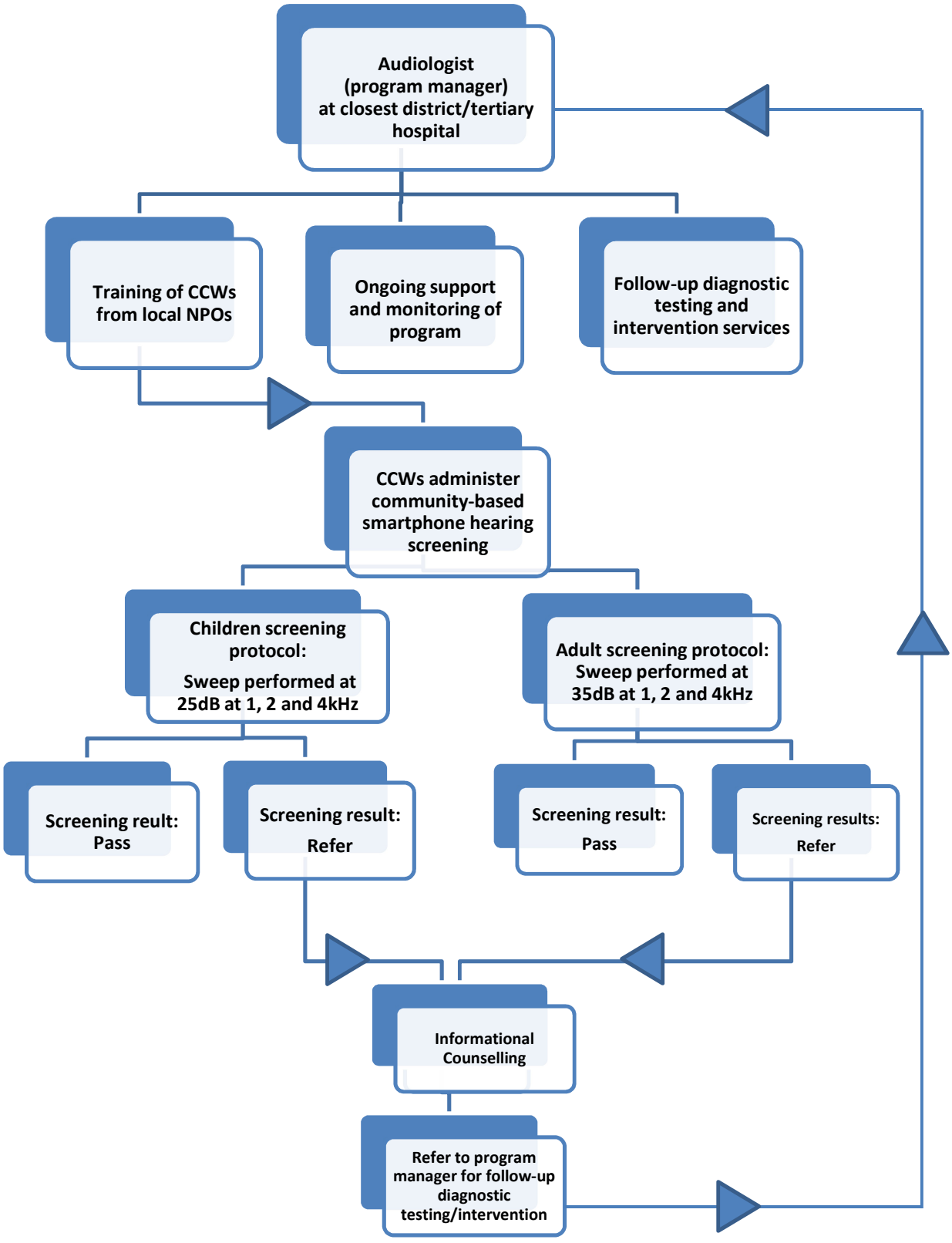

Figure 2: Proposed model for a community-based hearing screening programme.

4.3 Critical evaluation

A critical evaluation is imperative in order to identify strengths and limitations of the study. These are described below.

Strengths of the study

Strengths of the current study include the following:

- There is limited research available on community-based programmes for detection and diagnosis of hearing loss, particularly within vulnerable populations in sub-Saharan Africa (Chadha, 2013; Yousuf Hussein et al., 2016). Therefore this study is the first report on an mHealth assisted hearing detection and diagnosis programme within a vulnerable community using minimally trained CCWs.
- This study provides a baseline regarding the clinical efficacy of community-based hearing screening programmes within vulnerable communities, and provides information which may guide future research and hearing screening programmes.
- This study demonstrated that non-specialized personnel can successfully screen for hearing loss within vulnerable populations, thereby reducing the demands placed on the limited number of available hearing health care professionals.
- Hearing screenings were conducted on a large sample size, ensuring more accurate analysis.
- This study also determined the diagnostic outcomes of referred participants, allowing for appropriate interventions and recommendations to be made.
- Lastly, current information regarding the knowledge of CCWs concerning hearing health care is often limited, particularly within developing countries. This study is the first to provide a baseline of current CCW knowledge of hearing health care within a vulnerable LMIC community setting.

Limitations of the study

Limitations of the current study include the following:

- The main limitation identified in the current study was the lack of further management of participants identified with hearing loss. Patients identified with hearing loss were referred for further intervention services, but it is unknown if these participants received the required intervention services.
- BC threshold audiometry could not be conducted.

4.4 Future research

Results from this study created a potential for future research regarding a number of aspects. The effectiveness of further developments to the hearScreen™ software should be determined. It is recommended that further developments to the hearScreen™ software display any improvements to a test operator's QI throughout a testing period. This may be beneficial in order to monitor progression following retraining. The integration of guidelines and informational counselling into the application may also assist CCWs and other generalist health care personnel in screening difficult-to-test populations, as well as in explaining the importance of hearing screening and what the hearing results mean (Yousuf Hussein et al., 2016). Secondly, additional research needs to be conducted on the use of BC automated threshold audiometry. Lastly, further investigation is needed into the impact intervention services have on an individual's quality of life by means of community member questionnaires and surveys.

4.5 Conclusion

Due to the high prevalence of hearing loss within vulnerable communities, access to ear and hearing health care services is crucial (Ndoleriire et al., 2013; Smith et al., 2017). This study demonstrated that the integration of a mHealth hearing solution operated by CCWs is a novel and feasible approach to decentralizing access to hearing health care services within vulnerable communities, reducing the demands placed on the limited number of available ear and hearing health professionals (Yousuf Hussein et al., 2016).

Furthermore, the quality control features integrated into the smartphone applications allows for monitoring of environmental noise levels and test operator performance as well as data surveillance. CCWs evidenced a positive attitude towards the

smartphone hearing screening programme and generally wanted to continue providing screening as part of their regular home-based services. All things considered, mHealth solutions integrated into community-based screening programmes may provide a cost-effective and sustainable means of providing access to hearing services within disadvantaged communities, thereby reaching a larger portion of the population.

CHAPTER 5
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CHAPTER 6

APPENDICES

Appendix A: Letter from Research Ethics Committee

Appendix B: Letter of permission to Future Families NPO

Appendix C: CCW informed consent

Appendix D: Adult participant informed consent

Appendix E: Parent/guardian informed consent

Appendix F: Assent from participant <18 years old

Appendix G: Referral letter

Appendix H: Pass letter

Appendix I: CCW 1st Questionnaire

Appendix J: CCW 2nd Questionnaire

Appendix K: Declaration against Plagiarism

Appendix L: Proof that article was submitted for publication

Appendix M: Letter indicating article is under review

APPENDIX A

Letter from Research Ethics Committee

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA

Faculty of Humanities
Research Ethics Committee

21 April 2017

Dear Ms van Wyk

Project:	**Supporting hearing health for vulnerable populations affected and infected by HIV/ Aids using mobile technologies**
Researchers:	**T van Wyk**
Supervisors:	**Prof D Swanepoel**
Department:	**Speech-Language Pathology and Audiology**
Reference number:	**13167911 (GW20170312HS)**

Thank you for your response to the Committee's letter of 4 April 2017.

The **Research Ethics Committee** notes that the outstanding permission from the *Future Families* organisation was submitted as requested. The research project was therefore given **final approval** at an *ad hoc* meeting on 21 April 2017. Data collection may commence.

Please note that this approval is based on the assumption that the research will be carried out along the lines laid out in the proposal. Should the actual research depart significantly from the proposed research, it will be necessary to apply for a new research approval and ethical clearance.

We wish you success with the project.

Sincerely

Prof Maxi Schoeman
Deputy Dean: Postgraduate and Research Ethics
Faculty of Humanities
UNIVERSITY OF PRETORIA
e-mail: tracey.andrew@up.ac.za

CC: Prof D Swanepoel (Supervisor)

Prof B Vinck (HoD)

APPENDIX B

Letter of permission to Future Families NPO

TO: FUTURE FAMILIES

RE: SUPPORTING HEARING HEALTH FOR VULNERABLE POPULATIONS AFFECTED AND INFECTED BY HIV/AIDS USING MOBILE TECHNOLOGIES

As a researcher from the Department of Speech-Language Pathology and Audiology, University of Pretoria, I would like to invite you to volunteer to participate in our research project on **supporting hearing health for vulnerable populations affected and infected by HIV/AIDS using mobile technologies.**

This letter serves to provide information to help you decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask. You should not agree to take part unless you are comfortable with what is expected of you.

We wish to utilize 15 community care workers from the Future Families organization to provide hearing screening services and complete a questionnaire regarding their perceptions and experiences of the community-based screening programme. The care workers will receive training from a qualified Audiologist on how to conduct the screening, and will make use of the six hearScreen™ devices on a rotation basis. The hearing screening usually takes between 3 to 5 minutes to complete and if a participant refers a screening test, diagnostic audiometry will be conducted and the participant will receive an appropriate referral for further testing or intervention. The care workers will need to provide consent to participate (see attached letter of informed consent for care workers) and only once consent has been provided will they be trained. Furthermore, all participants in the study will be required to provide informed consent. For child participants the parents/guardians will have to provide informed consent and the children will be required to provide assent to have their hearing screened and for allowing their results to be used for research purposes (see attached assent and informed consent letter to parent/guardians and adult participants).

Please note that the hearing screening information obtained will be used for research purposes. In this case all identifying information will be kept confidential and data-

analysis will be conducted anonymously. If the participant or parent/guardian of the child wants to withdraw from the research project at any time they may do so without any negative consequences. Data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes.

We trust that you will find the above in order and look forward to hearing from you regarding the provision of hearing screening services conducted by care workers from the Future Families organization. Should you wish to take part in the above mentioned study, kindly complete the form below.

Should you require any further information regarding the research project, please do not hesitate to contact the research supervisor.

Yours sincerely,

Miss Tanith van Wyk
Researcher

Dr Faheema Mahomed-Asmail
Research Supervisor

Prof De Wet Swanepoel
Research Supervisor

Prof Bart Vinck
Head of Department

UNIVERSITEIT VAN PRETORIA
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Permission slip:

Herewith I Penelope Learmonth, Executive Director (state name and position) agree to take part in the above mentioned research study, and grant permission for the provision of hearing screening services conducted by care workers from the Future Families organization. I acknowledge that all information should be kept confidential and may be used for research purposes as specified above.

Signature:

2/8/2016.

Date:

APPENDIX C

CCW informed consent

Dear Care worker,

As a researcher from the Department of Speech-Language Pathology and Audiology, University of Pretoria, I would like to invite you to volunteer to participate in our research project on **supporting hearing health for vulnerable populations affected and infected by HIV/AIDS using mobile technologies.**

This letter serves to provide information to help you decide if you want to take part in this study. Before you agree you should fully understand what is involved. If you do not understand the information or have any other questions, do not hesitate to ask. You should not agree to take part unless you are comfortable with what is expected of you.

We wish to utilize your assistance in providing hearing screening services and to complete a questionnaire regarding your perceptions and experiences of the community-based screening programme. You will receive training from a qualified Audiologist on how to conduct the screening which will be part of the services you are currently providing to each family you see. The hearing screening usually takes between 3 to 5 minutes to administer on each individual who will be tested at the homes you are visiting and at community care centres in the Sunnyside area. If a child or adult participant refers a screening test, diagnostic audiometry will be conducted at a later stage and the adult participant or parent/guardians of the child will receive a referral text message. You will need to provide informed consent to participate in this study and only once consent has been provided you will be trained. Furthermore, all participants in the study will be required to provide informed consent. All adult participants will be required to provide consent and all children will be required to provide assent along with their parent/guardians providing informed consent for allowing their results to be used for research purposes (see attached assent and informed consent letter to parent/guardians and adult participants).

Please note that the hearing screening information obtained will be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. If the parent or child wants to withdraw from the research study at any time they may do so without any negative consequences.

With regards to the questionnaire you will need to fill out, it will take 10 minutes of your time. The results of the questionnaire will enable us to support and assist families in the future to promote healthy hearing. We will be available to help you with the questionnaire should you require any assistance. Please note that the results of the questionnaire obtained will be used for research purposes. In this case all identifying information will be kept confidential and data-analysis will be conducted anonymously. Participation in this research project is completely voluntary, therefore should you wish to withdraw from the research study at any stage you may do so without any negative consequences.

All data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes. Should you require any further information regarding the research project, please do not hesitate to contact the research supervisor.

Should you wish to take part in this study, kindly complete the form below.
Thank you for showing interest in this research project.

Yours sincerely,

Miss Tanith van Wyk
Researcher

Dr Faheema Mahomed-Asmail
Research Supervisor

Prof De Wet Swanepoel
Research Supervisor

Prof Bart Vinck
Head of Department

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Tel: +27 (12) 420 - 2355 (w)

Informed consent:

Herewith I, _____, (name) agree to take part in the above mentioned research project by assisting in conducting hearing screening services and completing a questionnaire. I acknowledge that all information should be kept confidential and may be used for research purposes as specified above.

_____ _____

Signature: **Date:**

APPENDIX D

Adult participant informed consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Participant,

Community care workers from the Future Families organization will be providing hearing screening services to the families they see. The hearing screening usually takes between 3 to 5 minutes to complete. Should you refer a screening test; diagnostic audiometry will be conducted at a later stage and where necessary you will receive an appropriate referral for further testing or intervention. Please note that the hearing screening information obtained may be used for research purposes. There are no risks involved in participating in the research study and no discomfort will be experienced. It should be noted that all identifying information will be kept confidential and data-analysis will be conducted anonymously. Participation in this research project is completely voluntary, therefore should you wish to withdraw from the research study at any stage you may do so without any negative consequences. Data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes.

Should you require any further information regarding the research project, please do not hesitate to contact the research supervisor.

Should you wish to make use of these services, kindly complete the form below.

Thank you for showing interest in this research project.

Kind regards

Miss Tanith van Wyk
Researcher

Dr Faheema Mahomed-Asmail
Research Supervisor

Prof De Wet Swanepoel
Research Supervisor

Prof Bart Vinck
Head of Department

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities

Prof Dr. B Vinck Msc, PhD
Professor in Speech-Language Pathology and Audiology
Head: Department of Speech-Language Pathology and Audiology
Chair: Applied Social Sciences Disciplinary Cluster
Email: bart.vinck@up.ac.za
Tel: +27 (12) 420 - 2355 (w)

Informed consent:

Herewith I, _____ (name), grant permission that hearing screening may be conducted on me, and I acknowledge that the information may be used for research purposes as specified above.

_____ _____

Signature of participant: **Date:**

APPENDIX E

Parent/guardian informed consent

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Dear Parent/Guardian

Community care workers from the Future Families organization will be providing hearing screening services to the families they see. The hearing screening usually takes between 3 to 5 minutes to complete. If your child refers a screening test, diagnostic audiometry will be arranged and conducted at a later stage and where necessary you will receive an appropriate referral for further testing or intervention. Please note that the hearing screening and diagnostic testing information obtained may be used for research purposes. There are no risks involved in participating in the research study and no discomfort will be experienced. It should be noted that all identifying information will be kept confidential and data-analysis will be conducted anonymously. Participation in this research study is completely voluntary, therefore should you or your child wish to withdraw from the research study at any stage you may do so without any negative consequences to you or your child. Data will be stored at the Department of Speech-Language Pathology and Audiology at the University of Pretoria for 15 years for research and archiving purposes.

Should you require any further information regarding the research project, please do not hesitate to contact the research supervisor.

Should you wish to make use of these services, kindly complete the form below.
Thank you for showing interest in this research project.

Kind regards

Miss Tanith van Wyk
Researcher

Dr Faheema Mahomed-Asmail
Research Supervisor

Prof De Wet Swanepoel
Research Supervisor

Prof Bart Vinck
Head of Department

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Prof Dr. B Vinck Msc, PhD
Professor In Speech-Language Pathology and Audiology
Head: Department of Speech-Language Pathology and Audiology
Chair: Applied Social Sciences Disciplinary Cluster
Email: bart.vinck@up.ac.za
Tel: +27 (12) 420 - 2355 (w)

Informed consent:

Herewith I _____ (name) grant permission that hearing screening may be conducted on my child, _____ ,(name) and I acknowledge that the information may be used for research purposes as specified above.

_____ _____
Signature of parent/guardian: **Date:**

APPENDIX F

Assent of Participant <18 years old

I am a care worker; someone who wants to take care of you. I want to learn more about your hearing.

Earphones will be put on your ears so that you can hear very soft sounds.

You will have to listen very carefully to hear the sounds.

When you hear the sound you must tell me.

This test will not hurt.

If you want to stop the test you can tell me. I will not be cross with you.

If you want to help me to test your hearing, you must write your name below or draw a picture of yourself.

This is my name / this is a picture of me:

APPENDIX G

Referral letter

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Date: _____

Dear _____

Thank you for providing consent to undergo a diagnostic audiometry evaluation on the _____20__. During the evaluation it was noted that you should be referred for further intervention.

For this reason we would like to refer you to:

Professional person:		**Reason:**	
	Audiologist		Further diagnostic hearing assessments / Hearing aid fitting
	Ear-nose-and-throat specialist (ENT)		Excessive wax in ear
			Negative pressure in the middle ear
			Other _____

Contact details:

- **Audiology Department at Steve Biko Academic Hospital**
  Tel: 012 354 4293

- **ENT Department at Steve Biko Academic Hospital**
  Tel: 012 354 2709 / 012 354 3776

Attached are the results obtained. We urge you to attend to this matter as soon as possible.

Kind regards,

_____

Miss Tanith van Wyk
Researcher

Dr Faheema Mahomed-Asmail
Research Supervisor

Prof De Wet Swanepoel
Research Supervisor

Prof Bart Vinck
Head of Department

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
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APPENDIX H

Pass letter

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
Faculty of Humanities
Department of Speech-Language Pathology and Audiology

Date: _____

Dear: _____

Thank you for providing consent for your hearing to be assessed on the _____20__. Results obtained indicate that currently there is no problem with both your hearing and middle ear functioning, and therefore no further investigation is needed. It is recommended that you monitor your hearing with annual hearing assessments.

Kind regards,

_____
Miss Tanith van Wyk
Researcher

_____
Dr Faheema Mahomed-Asmail
Research Supervisor

_____
Prof De Wet Swanepoel
Research Supervisor

_____
Prof Bart Vinck
Head of Department

UNIVERSITEIT VAN PRETORIA
UNIVERSITY OF PRETORIA
YUNIBESITHI YA PRETORIA
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Prof Dr. B Vinck Msc, PhD
Professor in Speech-Language Pathology and Audiology
Head: Department of Speech-Language Pathology and Audiology
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Email: bart.vinck@up.ac.za
Tel: +27 (12) 420 - 2355 (w)

APPENDIX I

CCW 1st Questionnaire

Questionnaire 1: CCW Knowledge regarding Hearing Health Care

Adapted from: Yousuf Hussein et al. (2016)

Background information:

Gender:
DOB:
Date:
First language:

Please indicate your answer by means of a tick under the relevant box:

Questions	Yes	Unsure	No
General			
1. Have you worked with someone who has a hearing loss?			
2. Do you think community members need hearing health care services?			
Causes and Risk Factors			
3. Do you think a person can be born with a hearing loss?			
4. Do you think certain illnesses can cause a hearing loss?			
5. Can hearing loss affect some people more than others?			
Identification and Intervention			
6. Can hearing loss be identified at any age?			
7. Can hearing loss be treated?			
8. Will children with a hearing loss do well at school like normal hearing children?			

9. Can hearing loss impact listening in the classroom for children?			
10. Can hearing loss impact speech and language development?			
11. Hearing loss can impact your work.			
12. Can hearing loss impact social interactions with others?			
Attitudes			
13. I would like more information on hearing loss.			

APPENDIX J

CCW 2nd Questionnaire

Questionnaire 2: Experiences of Care Workers regarding the Community-based Screening Programme

Adapted from: Yousuf Hussein et al. (2016)

Background information:

Gender:
DOB:
Age: _____years _____months
First language:

Please indicate your answer by means of a tick under the relevant box:

Questions	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. Instructions for conducting the hearing test are straightforward for testers.					
2. The smartphone hearing test is easy to administer on adults.					
3. The smartphone hearing test is easy to administer on children.					
4. The smartphone hearing test is quick to administer.					
5. Community members need hearing health care services.					
6. Community members were positive about receiving a smartphone hearing test.					
7. Community members trust the results of the					

smartphone hearing test.					
8. I trust the results of the hearing test.					
9. The hearing test is important for community screening.					
10. I would like to continue providing a hearing test as part of my service.					

APPENDIX K

Declaration against plagiarism

UNIVERSITY OF PRETORIA

FACULTY OF HUMANITITES

DEPARTMENT OF SPEECH-LANGUAGE PATHOLOGY AND AUDIOLOGY

I (full names) Tanith van Wyk

Student number: 13167911

Subject of the work: Masters Dissertation

Declaration

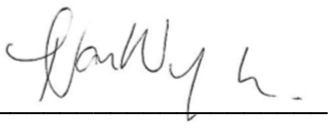
1. I understand what plagiarism entails and am aware of the University's policy in this regard.

2. I declare that this proposal is my own, original work. Where someone else's work was used (whether from a printed source, the internet or any other source) due acknowledgement was given and reference was made according to departmental requirements.

3. I did not make use of another student's previous work and submitted it as my own.

4. I did not allow and will not allow anyone to copy my work with the intention of presenting it as his or her own work.

Date: November 2018

Signature: 

APPENDIX L

Proof that article was submitted for publication

International Journal of Audiology - Manuscript ID TIJA-2018-09-0284

From: International Journal of Audiology (onbehalfof@manuscriptcentral.com)

To: tanithvanwyk@yahoo.com

Date: Friday, September 21, 2018, 1:18 PM GMT+2

MS: Supporting hearing health in vulnerable populations through community care workers using mHealth technologies
MS#: TIJA-2018-09-0284

21-Sep-2018

Dear Miss van Wyk:

This letter will acknowledge the successful online submission of the above listed manuscript to the International Journal of Audiology. The manuscript will soon be forwarded to an associate editor to oversee the review and obtain editorial comments from expert reviewers. Should you have questions, feel free to contact the editorial office (editor-ija@utdallas.edu). Please reference the manuscript number in any correspondence. You can also view the status of your manuscript at any time by checking your Author Center after logging in to https://mc.manuscriptcentral.com/tija.

It is the goal of the International Journal of Audiology to provide each manuscript with a comprehensive and expeditious peer review. You will be contacted upon completion of the initial review.

Thank you for considering IJA for your submission.

Sincerely,

Ross J. Roeser, Ph.D.
Editor-in-Chief

APPENDIX M

Letter indicating article is under review

International Journal of Audiology | Update on submission TIJA-2018-09-0284

From: International Journal of Audiology (onbehalfof@manuscriptcentral.com)

To: tanithvanwyk@yahoo.com

Date: Friday, September 28, 2018, 6:36 PM GMT+2

28-Sep-2018

Dear Miss Tanith van Wyk

As a courtesy, and to keep you informed, this is an automatic notification that your submission to the International Journal of Audiology has progressed to the next step of the peer review process and assigned to an IJA Associate Editor.

The goal of the IJA peer review process is to provide a thorough review of all submissions as expeditiously as possible.

Sincerely,
IJA Editorial Staff